IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE JENNIFER L. HALL
FROM BINDU A. PALAPURA, ESQUIRE

OF COUNSEL:

Jay P. Lefkowitz, P.C.
Jeanna M. Wacker
Benjamin A. Lasky
Sam Kwon
Christopher J. Citro
Ashley Cade
Matthew Lembo
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
Tel: (212) 446-4800

Bryan S. Hales
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862-2000

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyrne@potteranderson.com

Attorneys for Defendant Eagle Pharmaceuticals Inc.

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6914232 / 45185

Potter Anderson Corroon LLP

1313 North Market Street
P.O. Box 951
Wilmington, DE 19801- 0951
302 984 6000
www.potteranderson.com

Bindu A. Palapura
Partner
Attorney at Law
bpalapura@potteranderson.com
302 984-6092 Direct Phone
302 658-1192 Firm Fax

October 27, 2020

VIA ELECTRONIC FILING
The Honorable Jennifer L. Hall
United States Magistrate Judge
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

[redacted]

Re: *Par Pharm., Inc. v. Eagle Pharm., Inc.*, C.A. No. 18-823-CFC-JLH

Dear Magistrate Judge Hall:

I write in support of Defendant Eagle's request (D.I. 207) to: (1) strike Plaintiffs' expert Dr. Kirsch's report(s) raising untimely infringement theories, or allow Eagle's expert Dr. Park to respond; (2) supplement Eagle's invalidity expert reports to address Par's late-produced prior art sales records, and new infringement theories; and (3) take a supplemental deposition of Dr. Kirsch.

Background: Par alleges Eagle's proposed generic vasopressin product will infringe three patents claiming vasopressin compositions and their use to treat hypotension. Vasopressin has been used to treat hypotension for decades. Par's predecessor JHP sold an unapproved vasopressin product, "Pitressin," for years before the patents-in-suit. Many other companies sold unapproved vasopressin as well. But early last decade, the FDA began encouraging NDA filings for unapproved drugs, offering to remove competing formulations from the market in return for these filings. In September 2012, JHP [redacted] The FDA approved the NDA in 2014, and Par launched "Vasostrict." The FDA then removed all other vasopressin products from the market, [redacted] Both Pitressin and original Vasostrict are prior art to the patents-in-suit and so can be used to invalidate them.

Several years later, Eagle's joint venture partner began developing a generic version of original Vasostrict. [redacted] no patent-in-suit had issued and the lone published application had claims with no pH limitation. The patents arise from the purported discovery that increasing the pH from the [redacted] of prior art Pitressin and original Vasostrict, to pH 3.7–3.9, improves stability. Par alleges a ***reformulated*** Vasostrict (pH 3.8), launched in 2017, embodies the patents, while [redacted] do not. This creates several problems for Par: First, [redacted] Second, Par's recent, late-produced records show that [redacted]

In his opening infringement report, for the pH limitations, Par's expert Dr. Kirsch relied on [redacted] Eagle's expert Dr. Park responded that

[redacted] Ex. 2, ¶¶ 94, 146–157. In reply, Dr. Kirsch challenged [redacted] but again ignored [redacted]. Ex. 3, ¶¶ 32–38. Expert discovery closed in February 2020. The May 2020 trial was later continued due to the pandemic.

Par's Untimely Infringement Theories: As agreed, Eagle continued to produce pH data generated during the batches' shelf-life, and, on May 5, submitted a two-paragraph Park report confirming [redacted]. Ex. 4. Faced with these data, on May 8, [redacted] Ex. 5. Attempting to avoid dispute, Eagle initially did not object and instead Dr. Park responded to the new theory on June 8. Ex. 6. Par did not object. But on July 16, [redacted] data. Ex. 7. Eagle objected to yet another new theory, Ex. 8, but proposed a compromise: Eagle would not object if [redacted] Ex. 10.

Par's Untimely Invalidity Production: On August 3, with the question of a further deposition still open, out of the blue and over 9 months after the close of fact discovery, [redacted] Ex. 14. During discovery, [redacted]. Eagle's experts had identified a number of batches having a pH in the claimed range, including [redacted]. Ex. 11, ¶¶ 119–30; Ex. 12, ¶¶ 150–55. But Par denied that [redacted] Ex. 13, ¶¶ 111–12. Thus, Eagle's experts focused on [redacted] Ex. 11, ¶¶ 127–29. Par's August 3 production shows that [redacted] Ex. 15; D.I. 204. Importantly, [redacted] Ex. 13, ¶¶ 108–10. But Par objected to Eagle serving supplemental reports addressing [redacted]. Ex. 15.

Supplemental Reports: On September 16, Eagle's Dr. Park responded to [redacted], and its experts Park and Chyall addressing [redacted] Exs. 16–19. Par objected, stating that the May 8 Kirsch report should be the last permitted on infringement, while not addressing invalidity at all. Ex. 20. After another meet-and-confer, Eagle filed this motion. Par refused to seek leave for the May 8 or July 16 Kirsch reports, and declined to join Eagle's motion. Ex. 21. Par is not seeking to strike Eagle's supplemental reports. For the Court's convenience, a timeline of events is in Appendix A.

Argument: After expert discovery closed, "[n]o other expert reports [were] permitted without either the consent of all parties or leave of the Court." D.I. 20, ¶ 11.a. "Good cause" to modify the schedule for supplemental expert reports "is present when the schedule [could not] be met despite the moving party's diligence." *Meda Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2016 WL 6693113, at *1 (D. Del. Nov. 14, 2016); Fed. R. Civ. P. 16(b)(4). Courts also consider the *Pennypack* factors, *i.e.*: (1) prejudice to the other party; (2) ability to cure any prejudice; (3) potential to disrupt orderly and efficient trial; (4) presence of bad faith by the disclosing party; and (5) importance of the evidence. *See Acceleration Bay LLC v. Activision Blizzard Inc.*, 2019 WL

4194060, at *2 (D. Del. Sept. 4, 2019). Under these standards, Eagle's requests should be granted.

Regarding infringement, Eagle never consented to Dr. Kirsch's May 8 report—[redacted]—without Dr. Park having an opportunity to respond. And Par refused to seek leave for it. Without consent or leave, the May 8 Kirsch report is impermissible and should be stricken. And once that report is stricken, there is no need to consider permissibility of the June 8 and September 16 Park, and July 16 Kirsch, reports that followed.

If the May 8 Kirsch report is permitted, Eagle should be allowed "to submit a supplemental expert report to reply to Dr. [Kirsch's] newly disclosed opinions." *Vectura Ltd. v. GlaxoSmithKline, LLC*, 2019 WL 1436296, at *2–3 (D. Del. Apr. 1, 2019). Par never objected to the responsive June 8 Park report. And Dr. Park obviously could not have responded earlier to a theory Par and Dr. Kirsch never disclosed. The *Pennypack* factors support Eagle too. Par cannot claim prejudice or bad faith when its own late-disclosed theories and lack of diligence created the need for the Park report. And Dr. Park's report is important to Eagle's case and will ***promote*** an orderly and efficient trial, as it will allow Eagle to respond to Dr. Kirsch's new theories at trial. Par's contention that it should be permitted to inject [redacted] into the case without response defies logic.

If the May 8 Kirsch report is admitted, then admitting the June 8 Park report should be the end of it. But Par did not stop there, instead submitting the July 16 Kirsch report raising [redacted] that could have been raised during expert discovery, and no later than the May 8 report. Eagle objected. Ex. 8. Par would not agree to Eagle's compromises, and declined to request leave for the report. Exs. 10, 20, 21. Absent consent or leave, the report should not be permitted. D.I. 20, ¶ 11.a. If it is, however, Dr. Park's September 16 response also should be allowed for the same reasons discussed above. Ex. 17. Indeed, Par already agreed. Exs. 10, 20. Finally, to the extent Dr. Kirsch is permitted to testify to one or both new theories, Eagle should in fairness be permitted to take a limited, supplemental deposition on them. *See Vectura*, 2019 WL 1436296, at *2–3 (permitting supplemental deposition on expert's new opinions).

Regarding invalidity, good cause also exists for Eagle's supplemental invalidity reports. Had Par timely produced [redacted] Eagle's experts could have addressed them earlier. Par cannot rely on its own discovery failures to deny Eagle these strong invalidity positions. Par has not identified anything objectionable in the supplemental reports in any event. Ex. 20. Again, *Pennypack* supports Eagle. Par cannot claim prejudice or bad faith when the need for the reports is based on its own discovery failures. Eagle's discovery requests specifically sought [redacted]. Ex. 22. Par was obliged to search for and produce responsive documents. Yet it took Par until August of this year—about 10 months after the close of fact discovery, and three months after trial was to have taken place—for Par to finally do so. Thus, if anything, it is ***Par*** that acted in bad faith through late disclosures.

The supplemental opinions will not disrupt trial as they merely apply the experts' existing theories to the new evidence. Finally, the supplemental opinions are important to Eagle. [redacted] And Eagle's experts should be allowed to take [redacted] into account on validity, where "[i]t is axiomatic that claims are construed the same way for both invalidity and infringement." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003).

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

BAP:nmt/6914232/45185

Enclosures
cc: Counsel of Record (via electronic mail)

APPENDIX A

Date	Key Events
Feb. 2020	Close of expert discovery
5/2/2020	Park supplemental report presenting new data
5/8/2020	Kirsch supplemental infringement report
6/8/2020	Park supplemental responsive non-infringement report
7/16/2020	Kirsch supplemental reply infringement report
7/29/2020	Eagle objects to Kirsch supplemental reply infringement report
8/3/2020	Par produces [redacted]
8/20/2020	First meet-and-confer
9/16/2020	Park supplemental sur-reply non-infringement report
	Park and Chyall supplemental invalidity reports
9/24/2020	Par objects to service of supplemental reports
10/13/2020	Second meet-and-confer
10/21/2020	Eagle files motion for a discovery teleconference